MagSense™ Technology
Early detection of cancer through targeted imaging

ASX: IBX

www.imagionbiosystems.com
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IMAGION BIOSYSTEMS AT-A-GLANCE

New medical imaging technologies for the early detection of cancer

Imagion Biosystems
ASX:IBX
Australian Medical Device Company
developing bio-safe medical imaging technologies.

Market cap: ~$14.8 million
Net cash at 31 Dec 2019: $3.4M
Listed on the ASX: June 2017
R&D operations: San Diego
Registered office: Melbourne

Recent Milestones:
February 2020
Commenced GMP manufacturing

October 2019
Scientific Advisory Board (SAB) established

July 2019
Received “Breakthrough Device”
designation by U.S. FDA

- Innovative **medical imaging** using **magnetic nanoparticles** to identify and stage cancer early

- **Proprietary** MagSense™ technology is **non-invasive** and provides more specific & sensitive detection for cancer than current imaging technologies

- **Multiple commercial opportunities:**
  - Proprietary MagSense™ imaging technology
  - Magnetic Resonance Imaging (MRI) contrast agent
  - Therapy and/or drug delivery

- MagSense™ technology **complements existing imaging** and is more cost effective than many existing imaging technologies

- **First-in-human** studies on-track for 2020 – targeting metastatic breast cancer

Patents are already issued, or are pending, in all the major markets, making the lion's share of the global markets available for commercialization.

*Patents are valid through 2029.*

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A GROWING GLOBAL HEALTH PROBLEM

1 in 3 people are affected by cancer

$100B CANCER DIAGNOSTICS MARKET

Each year cancer kills 9 million people

$100B spent annually to diagnose or detect cancer, yet cancer continues to be a leading cause of mortality and morbidity

Millions (USD)

- Blood
- Pancreatic
- Kidney
- Ovarian
- Liver
- Prostate
- Colorectal
- Breast
- Lung

$3,055
$4,583
$5,908
$7,246
$8,850
$9,632
$15,541
$20,136
$26,044

CLEAR UNMET MEDICAL NEED

50 years since last new imaging technology was introduced

“Despite technical advances in many areas of diagnostic radiology, the detection and imaging of human cancer remains poor.”

MEDICAL IMAGING BREAKTHROUGH

MagSense™ Technology will transform cancer diagnosis

- **Non-invasive** – a safe and non-surgical solution to detect cancer
- **No radioactivity** - uses bio-safe magnetic nanoparticles to “tag” cancer cells
- **Platform technology** – can be used for many cancers as well as other diseases, e.g. infection and cardiovascular
- **Proprietary** - patent issued in most major global markets
- **Breakthrough** - technical feasibility and safety profile vetted, designated as a “breakthrough device” by FDA
- **First indication** – metastatic breast cancer, provides shortest path to commercialization
- **First-in-human** – ready for clinical studies - a catalyst for valuation and partnering
Better sensitivity could mean earlier detection

MagSense™ technology is expected to have sensitivity comparable to PET without use of radioactivity, making it better for routine use in early detection and resulting in more successful treatments and patient outcomes.

“Early detection of many diseases, particularly cancers, is key to successful treatment.”

Chemical Reviews 2015 Nanoparticles in Medicine Vol 115
The MagSense™ HER2 Metastatic Breast Cancer Test

- Works within current standard cancer diagnosis and staging protocols.
- Replaces current non-functional imaging such as MRI or ultrasound used to assess for enlarged lymph nodes but which cannot determine if tumor cells are present.
- Would eliminate unnecessary biopsies for patients that do not have metastatic spread to the lymph nodes.
- Would reduce incidence of lymphedema and associated morbidity.

The MagSense™ system and test has been designated by the FDA as a “Breakthrough Device” - reserved for products that provide for more effective treatment or diagnosis.
BROAD COMMERCIAL APPLICABILITY

Can be used for many types of cancer and at multiple stages of diagnosis

MAGSENSE NANOPARTICLES

• Are bio-functionalized to ensure high specificity for targeting different types of cancers, or other diseases.

• Can be used at multiple stages including primary diagnosis, staging, and monitoring the effectiveness of therapy.

• Are compatible with Imagion’s proprietary MagSense technology and with existing installed MRI systems as an MRI contrast agent.

• Uses known safe materials, including iron-oxide cores which are already cleared for multiple clinical uses including therapeutic applications.

MULTIPLE CLINICAL TARGETS

- Breast cancer
- Lung cancer
- Ovarian cancer
- Prostate cancer
**COMPELLING BUSINESS MODEL**  
**Proprietary consumable drives growth & profitability**

**ONE INSTRUMENT**

- **US$500K Capital Sale**  
  50% Gross Margin

**MANY TESTS**

- HER2 Breast Cancer  
- Ovarian Cancer  
- Prostate Cancer  
- Lung Cancer

US$1,500 / Test  
80% Gross Margin

**PRINTER / INK REVENUE MODEL**

- 35% capacity utilization  
- A$2.2 million annual revenue per instrument

Revenue through licensing/partnership fees  
Royalties or revenue share on tests

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INVESTMENT RATIONALE

Strategic plan provides path to future products & shareholder value

STAGING BREAST CANCER
Reduce unnecessary surgery
$700M

TUMOR DETECTION
Breast, prostate, lung & ovarian
$7B

MRI CONTRAST
Safer alternative to current product, Gadolinium
>$3B

TREATMENT MONITORING
Monitor tumor size and adjust treatment accordingly
>$2B

DOCTORS OFFICE
Hand-held MagSense instrument
>$14B

DETECTION & THERAPY
Provide both detection & delivery of therapy
>$140B

Addressable Markets
MILESTONES AND VALUATION DRIVERS

Indicative development timeline and key inflection points*

Milestones Achieved in 2018-19

- Lead formulation identified
- Preclinical models validated
- Formulation pilot production
- Toxicity study successfully completed
- Clinical instrument design plan complete
- Pre-IDE submission to FDA
- “Breakthrough device” designation awarded by the FDA
- Scientific Advisory Board established to guide and de-risk activities

- First-in-human study in FY2020 – study duration expected to be 3-6 months.
  - First human data key validation point, paves way for discussion with commercial partners.
- GMP manufacturing of nanoparticles for use in human study key driver of schedule.
- FDA communication for approval to commence study in process, breakthrough status ensures expedited communication.
- Clinical site contract discussions initiated; MD Anderson and additional sites under consideration.

Results available as study is on-going

2018 - 2019
2020
2021

* This development timeline is indicative only, and subject to change.
SCIENTIFIC ADVISORY BOARD

Collective expertise in oncology, medical imaging, nanotechnology, clinical trial design

DR JOHN HAZLE
SCIENTIFIC ADVISORY BOARD CHAIR
• Board certified in medical physics
• 30 years in pre-clinical & clinical imaging research
• Chairs Cancer Research at UT Graduate School of Biomedical Sciences

PROF LISA HORVARTH
• Director, Department of Medical Oncology, Chris O’Brien Lifehouse
• Head of Clinical Prostate Cancer Research, Garvan Institute of Medical Research

DR ROBERT IVKOV
• Expertise in radiation oncology and development and characterization of magnetic nanoparticles

PROF ANDREW SCOTT AM
• Director, Department of Molecular Imaging, Olivia Newton-John Cancer Research Institute
• Experience in pre-clinical development and first in-human trials.

DR PAUL GRINT
• Expertise in commercialisation of molecules
• Over 20 years experience in biologics and small molecule R&D

World class scientific collaborations & partnerships:

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

UC San Diego School of Medicine

MONASH University

THE UNIVERSITY OF SYDNEY

Planet Innovation

NewPhase

GLOBAL CANCER TECHNOLOGY
EXPERIENCED BOARD & MANAGEMENT

Commercially focused team with deep industry & clinical experience

ROBERT PROULX
CHAIRMAN & CEO
- Operationally oriented executive
- 25 years in life science & medical devices
- Product development & commercialization

OLIVER STEINBACH
VP CLINICAL & REGULATORY AFFAIRS
- Over 20 years in pharmaceutical, diagnostics and medical devices

MICHAEL HARSH
NON EXEC DIRECTOR
- Former CTO of GE Healthcare
- 35 years in medical imaging product development

DAVID LUDVIGSON
NON EXEC DIRECTOR
- 35 years in pharma, medical devices
- Corporate strategy, M&A, & financing

BRONWYN LE GRICE
NON EXEC DIRECTOR
- 15 years in Australian commercial healthcare & technology markets

BRIAN CONN
CFO
- CFO for early & growth stage biotech
- 25 years raising both public & private capital & M&A

MARIE ZHANG PHD
VP R&D
- 20 years in drug development
- Leadership in early stage and startup founder

MARK VAN ASTEN
NON EXEC DIRECTOR
- Strong track record in diagnostics & healthcare
- 25 commercializing diagnostic products

JOVANKA NAUMOSKA
NON EXEC DIR & COSEC
- Australian attorney with expertise in regulatory compliance, governance & risk management

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**CAPITAL STRUCTURE**

No debt, one class of common stock

<table>
<thead>
<tr>
<th>Ordinary shares on issue</th>
<th>511.28M*</th>
</tr>
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<tbody>
<tr>
<td>Share price (26 Feb 2020)</td>
<td>0.029</td>
</tr>
<tr>
<td>Average daily volume</td>
<td>7.2M</td>
</tr>
<tr>
<td>Market capitalization (26 Feb 2020)</td>
<td>14.83M</td>
</tr>
<tr>
<td>Net cash (31 Dec 2019)</td>
<td>$3.4M</td>
</tr>
</tbody>
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**Major Shareholders * (as of 26 Feb 2020)**
- Manhattan Scientifics Inc: 12.5%
- Drake Special Situations LLC: 4.89%
- Kenneth James Baker: 3.38%
- Kemper Shaw: 2.89%
- Board of Regents Univ Texas: 2.06%

Management and Board hold 0.36% of ordinary shares on issue. Does not include unvested ISO and Long-Term Incentive Plans, which allocates a total of 12,100,000 shares to the Key Management Group and a total of 3,450,000 shares to NEDs and employees, on vesting schedule or as performance rights.
INVESTMENT HIGHLIGHTS

LARGE OPPORTUNITY
$100B cancer diagnostic market
Growing 7% annually
Medical imaging commands largest share
Huge medical need for early diagnosis

UNIQUE TECHNOLOGY
New form of medical imaging
Molecularly specific & non-invasive
More sensitive than current methods
Protected by eight patents

COMMERCIAL STRATEGY
$2B initial market focus
Applies to many types of cancer
Printer-ink revenue model
Potential for therapeutics & research markets

READY TO ENTER THE CLINIC
Technical feasibility demonstrated
Safety profile of technology vetted
FDA “breakthrough device” designation
First-in-human data readout expected in 2020

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**HOW IT WORKS**

Bio-safe magnetic nanoparticles are attracted to the tumor and detected

- Nanoparticles, specific for the cancer, bind to tumor cells.
- Nanoparticles demagnetize or “relax” after exposure to a low magnetic field.
- Nanoparticles attached to cancer cells “relax” more slowly than particles in circulation acting as a magnetic beacon.
- Ultra-sensitive detectors locate the presence of attached nanoparticles.
PRE-CLINICAL RESEARCH

Product performance verified in pre-clinical models

SPECIFICITY
• In vitro cell based studies confirm specificity for HER2 expressing breast cancer cells.
• Animal studies confirm in vivo selectivity for HER2 expressing breast cancer tumours.

SENSITIVITY
• In vitro cell based studies indicate target level of sensitivity should be achievable.
• In vitro and in vivo animal studies indicate little non-specific background.

SAFETY
• GLP-compliant toxicology and toxicokinetic study showed no adverse effects.
IMPROVING MRI DIAGNOSTIC UTILITY

Additional commercial opportunity as an MRI contrast agent

• MagSense™ iron oxide nanoparticles generate T2* MRI contrast even at low concentrations.

• Targeted nanoparticles would change MRI from identifying a region of interest to imaging for specific tumor cells.

• MRI utility provides additional or alternative development path expanding and further de-risks venture investment. *

• Favorable commercialization path eliminates need to sell new instrumentation and leverages installed base of >5000 clinical MRI scanners.

MRI Contrast Agents -$3B Annual Market

* Further development of the MRI contrast agent capabilities is not the current priority due to the more favorable regulatory environment for the MagSense technology as a medical device.